REMARKS

Claims 1-15 and 19-23 have been amended. Claims 1-23 remain pending in the above-identified application. No new matter has been added. Applicants thank the Examiner for the allowance of claims 13-18. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 1, 2 and 12 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Published Application No. 2002/0099296 to Flaherty et al. ("Flaherty"). (**See** Office Action, p. 2).

Flaherty discloses a method and apparatus for the non-invasive determination of blood pressure. (**See** Flaherty, ¶ [0001]). More specifically, Flaherty teaches a method and apparatus for quickly determining a blood pressure value at a specific time. (**Id.** at ¶ [0008]). An external pressure is supplied to the artery so that the artery experiences a range of transmural pressures. The external pressure is set so that a known event, or marker, will occur during a measurement period. The measurement period is a short period of time that typically can be a cardiac cycle or a few cardiac cycles. The value of the external pressure at the time of the event allows for the calculation of an arterial pressure associated with the time of the event or an earlier or later time in another cardiac cycle. (**Id.**).

In the apparatus of Flaherty, an exciter can optionally be used to induce a high frequency pressure perturbation on the artery. In the "pressure-volume embodiments" of Flaherty, an arterial pressure dependent signal and an arterial volume dependent signal are used to produce a curve of a volume indication versus a pressure indication. (**Id.** at ¶ [0018]). The maximum rate of change of

this curve will be at a transmural pressure approximately equal to zero. This means that, when the arterial pressure dependent signal has a value such that the compliance related value has a maximum, the arterial pressure is approximately equal to the externally-applied pressure. The time at which the transmural pressure is approximately equal to zero is obtainable, since the system knows the value of the pressure-dependent signal at different times. (Id.).

To establish the volume/pressure curve, Flaherty uses arterial (a) a pressure-dependent signal and (b) a volume-dependent signal. To measure the arterial pressure-dependent signal, Flaherty uses a tonometer or other pressure sensors, or a system which measures the velocity of propagation of a pressure wave through the artery since the pressure wave velocity is monotonically related to the arterial pressure. (Id. at ¶¶ [0020]-[0021]). To measure the arterial volume-dependent signal, Flaherty uses a plethysmograph to get a volumetric indication of the volume of the artery or a pressure transducer connected to the cuff used to apply the external pressure to the artery. (Id.). In fact, Flaherty teaches to find a zero-transmural pressure by plotting a volume/pressure curve obtained as a result of applying onto an artery disturbances that produce pressure-dependent responses and volume-dependent responses respectively for known volume and pressure conditions. (Id. at ¶ [0063]).

Claim 1 recites system for monitoring relaxation of a given muscle of a living subject, comprising: "means for applying *muscle-activating stimulation signals* to the living subject's body via at least one electrode to stimulate the given muscle of the living subject " and "means for sensing *pressure waveform signals* produced by the given muscle of the living subject *in response to the applied stimulation signals*" in combination with "means for processing the sensed pressure waveform signals to produce data *indicative of a level of*

relaxation of the given muscle of the living subject" and "means for displaying the data indicative of the level of relaxation of the of the given muscle of the living subject from the processing means."

According to the specification of the present invention, muscle-activating stimulation signals are applied to the body of the living subject to stimulate the given muscle of the living subject. (**See** Specification, p. 9, lines 13-23). In response to the muscle-activating stimulation signals, the given subject's muscle produce pressure waveform signals that are processed to produce data indicative of a level of relaxation of the given living subject's muscle. The data indicative of the level of relaxation of the given subject's muscle are finally displayed. (**Id.**).

In contrast to the present invention as recited in claim 1, Flaherty does not teach or suggest providing muscle-activating stimulation signals. The present invention uses phonomyography for monitoring relaxation of a given muscle of a living subject. It is respectfully submitted that Flaherty fails to teach what is phonomyography, i.e. stimulating a given muscle which produces, in response to the stimulation, a pressure wave such as a sound wave. In this respect, Flaherty fails to teach applying muscle-activating stimulation signals to the body of a living subject to stimulate a given muscle of the living subject. Flaherty only teaches applying to pressure excitations to an artery. Thus, it is respectfully submitted that Flaherty neither discloses nor suggests "means for applying muscle-activating stimulation signals to the living subject's body via at least one electrode to stimulate the given muscle of the living subject," as recited in claim 1.

In addition, Flaherty also fails to describe processing of the pressure waveform signals produced by the given subject's muscle in response to the

muscle-activating stimulation signal to produce data indicative of a level of relaxation of the living subject's muscle, and displaying of these data indicative of that level of relaxation. Flaherty teaches the processing of pressure/volume signals in view of non-invasively determining blood pressure in an artery. Thus, it is respectfully submitted that Flaherty neither discloses nor suggests "means for sensing pressure waveform signals produced by the given muscle of the living subject in response to the applied stimulation signals" and "means for processing the sensed pressure waveform signals to produce data indicative of a level of relaxation of the given muscle of the living subject," as recited in claim 1.

Based on the reasons discussed above, it is respectfully submitted that claim 1 is allowable. Claim 2 recites "at least one neurostimulator to apply *muscle-activating stimulation signals* to the living subject's body via at least one electrode to stimulate the given muscle of the living subject" and "at least one pressure waveform sensor to detect *pressure waveform signals produced* by the given muscle of the living subject *in response to the applied stimulation signals*" and "a processor of the detected pressure waveform signals to produce *data indicative of a level of relaxation* of the given muscle of the living subject." Thus, it is respectfully submitted that claim 2 is allowable for at least the same reasons as discussed above with reference to claim 1. Because claim 12 depends from, and, therefore includes the limitations of claim 2, it is respectfully submitted that this claim is also allowable.

Claims 1, 2, 10 and 12 stand rejected under 35 U.S.C. 102(b) as being anticipated by the article entitled: *The Mechanism of Low-Frequency Sound Production in Muscle*, by *Frangioni, John V. et al.* ("Frangioni"), published in *Biophys. J.*, May 1987, pp. 775-783. (**See** Office Action, p. 2).

Frangioni describes an experimental set-up wherein a bare gastrocnemius

muscle removed from of a frog (*Rana pipiens*) is immersed in a Ringer's solution bath kept at 20°C, wherein the sciatic nerve of the gastrocnemius muscle is preserved intact along the entire length of the femur. (**See** Frangioni, pp. 775-776; Fig. 1). The gastrocnemius muscle is then isometrically stimulated through electrodes that make contact with the sciatic nerve, wherein the cut end of the sciatic nerve is placed into a nerve holder made by machining an L-shaped groove into a Lucite block. (**Id**. at p. 776, left column). A hydrophone, also immersed in the bath with its tip pointing at the gastrocnemius muscle belly, is then used to record the sound produced by the gastrocnemius muscle as a result of the stimulation of the sciatic nerve by the electrodes. A hydrophone is a sound-to-electricity transducer for use in water or other liquids, such as the Model LC-10 quartz crystal hydrophone by Celesco Transducers Products, Inc. used in the experimental set-up of Frangioni. (**Id.** at p. 775, right column). The first objective of the experiment of Frangioni "was to test the hypothesis that a muscle actually does produce low-frequency sound in isolation of the rest of the body." (**Id.** at p. 775, left column, lines 23-25); in other words to demonstrate the existence of "phonomyography".

Frangioni fails to describe a system for monitoring relaxation of a given muscle of a living subject, in which the pressure waveform signals produced by the given muscle of the living subject in response to the muscle-activating signal are processed to produce data indicative of a level of relaxation of the given muscle of the living subject and in which the data indicative of the level of relaxation of the given subject's muscle are displayed. The purpose of the experiment of Frangioni is to determine whether a muscle stimulated through a nerve will produce sound waves. In Frangioni, the sound waves produced by the muscle are detected but there is no indication that such sound waves could eventually be processed to provide data indicative of the level of relaxation of a muscle, this time, of a living subject. Thus, it is respectfully submitted that

Frangioni neither discloses nor suggests "means for processing the sensed pressure waveform signals to produce data indicative of a level of relaxation of the given muscle of the living subject," as recited in claim 1. Accordingly, it is respectfully submitted that claim 2 is allowable for at least the same reasons as claim 1 and the rejection of claim 2 and all claims depending directly or indirectly therefrom (claims 10 and 12) should be withdrawn.

Claims 3-7, 19 and 20 stand rejected under 35 U.S.C. § 103(a) as obvious in view of Flaherty. (**See** Office Action, pp. 3-4).

As previously discussed, Flaherty fails to disclose or suggest "at least one neurostimulator to apply muscle-activating stimulation signals to the living subject's body via at least one electrode to stimulate the given muscle of the living subject" and "at least one pressure waveform sensor to detect pressure waveform signals produced by the given muscle of the living subject in response to the applied stimulation signals" and "a processor of the detected pressure waveform signals to produce data indicative of a level of relaxation of the given muscle of the living subject," as recited in claim 2. Because claims 3-7 depend from and include the limitations of claim 2, it is respectfully submitted that these claims are also allowable.

Claim 19 recites a method using phonomyography that includes the steps of "applying *muscle-activating stimulation signals* to the living subject's body via said at least one electrode to stimulate the given muscle of the living subject" and "sampling *pressure waveform signals* detected by said at least one pressure waveform sensor and produced by the given muscle of the living subject *in response to the applied muscle-activating stimulation signals*" and "processing the sampled detected pressure waveform signals to produce data *indicative of a level of relaxation* of the given muscle of the living subject." Thus, it is

respectfully submitted that claim 19 and all claims depending directly or indirectly therefrom (claim 20) are allowable for at least the same reasons as discussed above with reference to claim 1.

The Examiner has indicated that claims 13-18 are allowable and claims 21-23 would be allowable if rewritten. (**See** Office Action, pp. 4-5).

Claims 13-15, 21 and 22 have been amended as independent claims. Thus, it is respectfully submitted that claims 21, 22 and 23 (which depends from claim 22) are allowable.

CONCLUSION

In view of the above amendments and remarks, it is respectfully submitted that all of the presently pending claims are in condition for allowance. All issues raised by the Examiner having been addressed, an early and favourable action on the merits is earnestly solicited.

Respectfully submitted:

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